

**Extracorporeal Cardiopulmonary Resuscitation (ECPR) for Out-of-hospital
Cardiac Arrest (OHCA)
Virtual Workshop
National Heart, Lung, and Blood Institute
Date: August 23-24, 2021**

Workshop Objectives

Chairs: *Karl Kern, MD, University of Arizona and Laurie Morrison, MD, University of Toronto*

Specific aims:

- Review and consider the ARREST results in the context of other available data, including the EROCA trial and international experience
- Determine the state of the science and regulatory policy for ECMO-based resuscitation in OHCA
 - Cover where does ECPR-based resuscitation fit in the resuscitation ecosystem vs. expanded use of other proven therapies
- Consider the ethics of a sophisticated intervention that can't be delivered everywhere
- Discuss the research and health care delivery workforce implications
- Consider future research opportunities

Agenda Day 1

10:00 – 10:35 am Overview and Workshop Goals

10:00 am Welcome (10 min)
David Goff, MD, PhD, Director, Division of Cardiovascular Sciences (DCVS), NHLBI

10:10 am Overview and Goals (5 min)
George Sopko, MD, MPH, DCVS, NHLBI
Emily Tinsley, PhD, MS, DCVS, NHLBI
Kathleen Fenton, MD, MS, DCVS, NHLBI

10:15 am Cardiac Arrest: Public Health Perspective (20 min)
Leith States, MD, Acting Director, Office of Science and Medicine, DHHS

10:35 – 11:45 pm Session 1: State of Science– US and International Experience
Moderators: Tom Aufderheide, MD, Medical College of Wisconsin

1035-1045 Systematic Review of the current literature including the Arrest Trial: do we have enough science to support widespread implementation?
Mike Donnino, MD, Beth Israel Deaconess Medical Center, Boston

10:45 am ARREST Trial Panel (5 min each)

- Cardiology Perspective
Demetris Yannopoulos, MD, University of Minnesota
- EMS and Emergency Medicine Perspective
Thomas Aufderheide, MD, Medical College of Wisconsin
- FDA Regulatory Perspective
Catherine Wentz, MS, FDA

11:00 am EROCA Trial Panel (5 min)

- Implementation of a System of Care Perspective
Robert Neumar, MD, PhD, University of Michigan
- EMS and Emergency Medicine Perspective

Cindy Hsu, MD, PhD, University of Michigan

- 11:10 am British Columbia trial CPR (5 min) – trial update
Brian Grunau, University of British Columbia
- 11:15 am Prague OHCA Study (5 min) - unpublished trial results
Jan Belohlavek, MD, Charles University of Prague, Czechia
- 11:15 am *Discussion with chairs (30 mins) – focusing questions: What have learned from the trials’ design and results? Can we generalize the ARREST model and replicate the ARREST results at other centers? Should ARREST trial be “replicated” using a multicenter design?*
- 11:45 pm Break (45 min)**
- 12:30 – 13:10 pm Session 2: The value of registry data to advance the science and guide implementation.**
*Moderators: Alain Combes, (Pitié-Salpêtrière Hospital, Sorbonne Université, Paris
Catherine Wentz, MS, FDA*
- 12:30 pm ECPR Platform and Registry Panel (10 mins each except*)
- ECMO Databases in the US and Canada
Joe Tonna, MD MS, University of Utah
 - ECMO Databases in Europe
Wulfran Bougin, MD, University of Paris, France
 - SIREN Survey Results (*5 mins)
Cindy Hsu, MD, PhD, University of Michigan
 - SIREN Registry Design & Data Elements Standardization
Valerie Durkalski, PhD MPH, Medical University of South Carolina.
 - Feasibility of adding ECPR data points to existing registries
Bryan McNally, MD, MPH, Emory University
- 13:15 pm How does observational data help address the gaps in science (10 min each)
- What gap in ECPR resuscitation science will ECPR registry fill – utility from a scientist
Cliff Calloway, University of Pittsburgh
 - What gap in ECPR resuscitation science will ECPR registry fill – utility from a regulator
Nicole Gillette, FDA
- 13:35 *Discussion with chairs (30 mins) – focusing questions: what are the critical elements? How can we create a nationwide ECPR registry to collect uniform data on site volume, inclusion/exclusion criteria, transport time and distance of index OHCA and arrival to ED, and outcome? How do we modernize data collection (in-hospital and prehospital) for OHCA to advance resuscitation research goals? How do we recognize cardiac arrest as a reportable disease to facilitate comprehensive data collection and reporting?*
- 14:05 – 15:30 Session 3: Is the ARREST Model Generalizable?**
*Moderators: Betsy Hunt, MD, MPH, PhD, Johns Hopkins University
Raina Merchant, MD, MSHP, University of Pennsylvania*
- 14:00 ECPR Hardware –what are the current approved options available in the world and what subgroup of options are approved for use in the US and what is the next generation that is coming down the pipeline (10 min)

Andriy Batchinsky, MD, U.S. Army Institute of Surgical Research/Medical College of Wisconsin

- 14:10 Training Models –key training models and requirements to creating efficient teams in new environments –virtual simulation solutions to keep costs down and make it generalizable for urban and rural environments (10 min)
Jennifer Gurney, MD, US Army Institute of Surgical Research, Houston Texas
- 14:20- Organizational Approach to Implementation (5 min each)
- describe the organizational approach used clinically in the trial – identify strengths weaknesses threats opportunities
Demetris Yannopoulos, MD, University of Minnesota
 - What are the other possible approaches in other trials or jurisdictions – what has worked well and what has not and why – lessons learned and keys to success
 - *France – Alain Combes, MD, Sorbonne Université, Paris*
 - *Japan - Tsukasa Yagi, MD/Ken Nagao MD, Surugadai Nihon University Hospital, Tokyo*
 - ECPR implementation from the specialty perspective (5 mins each on what are the ways to engage, enable surgical support and keep the momentum and enthusiasm for an ECPR program)
 - *Karl Kern, MD, University of Arizona – based on CCU and STEMI experience*
 - *John Holcomb, MD University of Alabama at Birmingham - based on trauma experience*
 - *Jason Bartos, MD, University of Minnesota Role of Critical Care post ECPR and follow up – not for the feint of heart*
- 14:50 - 15:20 *Discussion with chairs (30 mins) – focusing questions: what are the essential implementation requirements for ECMO after cardiac arrest? What is the optimal algorithm that will be helpful to developing the appropriate and optimal guideline for ECPR supported early post OHCA care? How can an ECPR-based strategy be applied in pre-hospital setting to recruit truly eligible patients and improve outcomes?*

Agenda Day 2

- 10:00 – 11:00 am Session 4: Ethical Considerations for Inequities in Current OHCA Interventions and Survival Outcomes**
*Moderators: Bob Neumar, MD, PhD, University of Michigan
Audrey Blewer, MD PHD Duke University
Comilla Sasson, MD, PhD, University of Colorado Hospital*
- 10:00 am What models exist for successful implementation to address existing inequities in resuscitation outcomes (pre ECPR)? (10 mins)
Marina Del Rios, University of Chicago
- 10:10 am Identifying the unique equity issues with ECPR in the US? (10 mins)
Ahamed Idris, MD, University of Texas Southwestern (
- 10:20 am Suggest an implementation model and evaluation strategy that would address the equity issues with ECPR in the US? (10 mins)
Sarah Perman, MD, University of Colorado Anschutz Medical Campus
- 10:30 11:00 am Discussion with chairs (engage the international attendees in finding solutions) focusing questions: How do we address inequities in ECPR and optimize equitable access; How

can we integrate local emergency health care delivery and a highly experienced interventional team to provide ECPR and continuity of care from prehospital to ED/hospital settings for all patients? (30 min)

11:00 am

Break (10 min)

11:10 – 12:20 pm

Session 5: How to deliver ECPR in health care systems with resource limitations

Moderators: Brian Grunau, MD, University of British Columbia

Scott Youngquist, MD, University of Utah

11:10 am

Hub-ECPR centres of excellence and systems of care – what would this look like, and success and miseries in optimizing systems of care and centers of excellence. (10 min)

Cliff Calloway, University of Pittsburgh –

11:20 am

Spokes- is there a role for an ECPR prehospital system of care – preferred pathway – can we learn from the pediatric experience (10 min)

Betsy Hunt, MD, MPH, PhD, Johns Hopkins)

11:30 am-12:00

Discussion with Chairs (30 mins) focusing questions: how can we regionalize ECPR systems of care efficiently, effectively and equitably How can we develop and apply ECPR-based resuscitation program with inclusion of all community stakeholders (e.g., healthcare systems, EMS systems, governmental officials, hospital administrative leadership, and key clinical leaders) throughout various regions and resources to improve survival in sudden death/OHCA – what can we learn from Minnesota to bring the community together?

12:00 pm

Lunch break

13:00

Break outs: 5 interdisciplinary teams comprised of EMS EM Cardiology Surgery where registries and equity are represented.

Goal: Summarize the research gaps across the spectrum of ECPR implementation –the discussions will be managed by current sessions moderators with one recorder/presenter per break out team

Breakout 1: The value of registry data to advance the science and guide implementation

Breakout 2: Is the ARREST Model Generalizable?

Breakout 3: Ethical Considerations for Inequities in Current OHCA Interventions and Survival Outcomes

Breakout 4: How to deliver ECPR in health care systems with resource limitations

Breakout 5: Science of ECPR/ECMO

14:00

Report out (10 mins each) – 40 mins total

14:40-15:00

Chairs outline next steps – Consensus White Paper on Research Priorities in ECPR

Current list of potential participants

- **[Aufderheide, Thomas P., MD](#)**, Professor of Emergency Medicine and Associate Chair of Research Affairs, Medical College of Wisconsin, exp: EM, EMS, resuscitation, EFIC, ROC PI (Resuscitation Outcomes Consortium)
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- **[Bartos, Jason MD, PhD](#)**; Assistant Professor of Medicine, University of Minnesota; exp: ECMO, ECPR, cardiac critical care, resuscitation, advanced hemodynamic support, pulmonary embolus, and coronary artery disease, president of the Minnesota Mobile Resuscitation Consortium (MMRC)
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- **[Batchinsky, Andriy I, MD](#)**, Professor and Founding Director, Autonomous Reanimation and Evacuation (AREVA) Research Program, Geneva Foundation; Manager, Extracorporeal Life Support (ECLS) Capability Area, U.S. Army Institute of Surgical Research, Director, Autonomous Reanimation and Evacuation Research Program (AREVA), Brooks City Base, San Antonio, TX; exp: extracorporeal life support (ECLS) therapy and real-time critical care diagnostic tools, nonlinear analysis techniques to investigation of cardiovascular regulatory complexity during hemorrhagic shock, burn shock and resuscitation, ECMO expert presented at NIBIB/FDA/NIH workshop
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- **[Belohlavek, Jan, MD](#)**, Professor of Medicine; 1st Medical School, Charles University in Prague; exp: acute Cardiac Care , e-Cardiology, Acute Heart Failure, Interventional Cardiology, in charge of cardiac intensive care, ECMO team coordinator; refractory cardiac arrest, ECMO reperfusion, microcirculation, different ECMO settings; PI of the Prague OHCA study comparing hyperinvasive approach – ECPR to standard therapy in refractory cardiac arrest, COVID and ECMO.
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- **[Blewer, Audrey L. PhD MPH](#)**, Assistant Professor in Family Medicine and Community Health, Duke University School of Medicine; exp: epidemiologist and resuscitation scientist, bystander CPR disparities\
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- **[Bobrow, Bentley J., MD](#)**, Professor and Chair of Emergency Medicine, UT McGovern Medical School of Medicine; exp: Texas-Cardiac Arrest Registry to Enhance Survival (CARES) Program, out-of-hospital cardiac arrest, acute stroke, traumatic brain injury (TBI), and improvement of access to high-quality emergency care.
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- **[Donnino, Michael MD](#)**, Professor of Emergency Medicine , Director of the Center for Resuscitation Science and Director of Critical Care in Emergency Medicine; Beth Israel Deaconess Medical Center, Boston ; exp: clinical trials and clinical investigations in septic shock and cardiac arrest. In the field of

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- **[Grunau, Brian MD, MHSc](#)**, Assistant Professor, University of British Columbia (BC), Centre for Health Evaluation and Outcome Sciences (CHEOS); exp: director of the St. Paul's Hospital ECPR program for out-of-hospital cardiac arrest (OHCA), Co-Director | BC Resuscitation Research Collaborative (BC RESURECT), pre-hospital care, Resuscitation Innovation Lead, Emergency Medicine Network, regional program in partnership with BC Emergency Health Services
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- **[Gurney, Jennifer M., MD, FACS](#)**, COL, Medical Corps, US Army Surgeon, US Army Institute of Surgical Research and Chief, Defense Committee on Trauma Joint Trauma System; exp: ECMO, surgical critical care and trauma
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- **[Morrison, Laurie, MD](#)**, Professor and Chair, Acute Care and Emergency Medicine, University of Toronto, exp: Prehospital and transport medicine, resuscitation research, medical futility decision rules, emergency health care delivery, acute coronary syndrome, cardiac arrest, life threatening trauma, ECPR, feedback systems to paramedics, SCD data collection
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- **[Nagao, Ken, MD PhD](#)**, Lead researcher, Surugadai Nihon University Hospital , Tokyo, Japan; exp: Multicenter Registry Study With Therapeutic Hypothermia After Cardiac Arrest in Japan (J-PULSE-HYPO), [Duration of prehospital resuscitation efforts and neurologically intact survival after out-of-hospital cardiac arrest](#), Ventricular Arrhythmias, Sudden Cardiac Death (SCD), ECPR, monitoring brain tissue perfusion
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